NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders

January 20, 2000

2029 '00 JAN 24 A9:11

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma

Dear Sir/Madam:

Thank you very much for the opportunity to allow the National Hemophilia Foundation (NHF) to submit comments on this draft guidance for industry. NHF is quite pleased with the proposal and would like to respond with its support.

The NHF has long supported regulations mandating the use of nucleic acid testing (NAT) for blood donor and plasma pool screening. We believe that there is ample scientific evidence to support the contention that viral antigen testing alone may fail to identify potentially infectious products due to low levels of virus that may be present in plasma during the window periods of early infection or in a late chronic carrier stage. Because of its superior sensitivity, NAT can reduce the window periods for HIV and HBV and detect potentially infectious units from donors who test seronegative by currently available antigen testing criteria. NAT may especially important for the detection of hepatitis C- and parvovirus B19-contaminated donations, blood-borne diseases for which viral antigen testing is not currently available.

Currently, several manufacturers of plasma derivatives in the United States and Europe have voluntarily begun to employ NAT, often as an additional lot-release test, to further increase the safety of their products. The NHF agrees with the FDA's position that final container testing is not likely to be as sensitive as the testing of individual donations or smaller pools. Further, final container testing may lead to the unnecessary destruction of large plasma pools and does not easily permit donor identification.

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116 West 32nd Street • 11th Floor
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(800) 42-HANDI • (212) 328-3700 • fax (212) 328-3777
www.hemophilia.org • info@hemophilia.org

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As for any biological testing, a variety of quality control procedures are required to assure effectiveness, reproducibility and safety in the specific application for which their use is intended. For this reason, the NHF supports the FDA's position that NAT testing procedures and kits should be licensed and subject to standard regulation and oversight. The NHF recognizes that the optimal size of the pool appropriate for NAT remains to be determined. Nonetheless, we agree with the FDA's position that the identification of virus-positive donors is extremely important, not just to improve the safety of the blood supply, but in order to offer appropriate counseling, treatment and blood donation deferral. We also recognize that objections have been raised concerning the application of NAT due to concerns of cost-effectiveness. However, we maintain that industry has the obligation to implement the best available procedures to ensure the safety of the blood supply and these should be subject to FDA regulation and oversight.

In conclusion, we wish to reiterate NHF's support for this draft guidance and applaud the FDA for its furtherance of the technology to ensure the integrity and safety of the nation's blood supply.

Sincerely,

Stephen E. Bajardi
Executive Director & CEO

Bruce M. Ewenstein, MD, PhD
Bruce M. Ewenstein, M.D., Ph.D.
Co-Chair
NHF Blood Safety Working Group

SB/BME/pc

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New York, NY 10001
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